

**EAR WAX REMOVAL AID DROPS- carbamide peroxide liquid  
PHARMACY VALUE ALLIANCE, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Premier Value Ear Wax Removal Aid Drops**

***Active ingredient***

Carbamide peroxide 6.5%

***Purpose***

Earwax removal aid

***Uses***

For occasional use as an aid to soften, loosen and remove excessive ear wax

***Warnings***

**Ask a doctor before use if you have**

- ear drainage or discharge
- ear pain
- irritation or rash in the ear
- dizziness
- an injury or perforation (hole) of the eardrum
- recently had ear surgery

**When using this product**

avoid contact with the eyes

**Stop use and ask a doctor if**

- you need to use for more than four days
- excessive ear wax remains after use this product

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away at (1-800-222-1222).

***Directions***

**FOR USE IN THE EAR ONLY.**

- **Adults and children over 12 years of age:**
- tilt head sideways
- place 5 to 10 drops into ear canal.

- tip of applicator should not enter ear canal.
- keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear.
- Use twice daily for up to four days if needed, or as directed by a doctor.
- Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe.

**Children under 12 years of age:** consult a doctor.

### ***Other information***

- Store at room temperature
- Avoid exposing bottle to excessive heat and direct sunlight
- Store bottle in the outer carton
- Product foams on contact with earwax due to release of oxygen. There may be an associated “cracking” sound.
- Keep cap on bottle when not in use

### ***Inactive ingredients***

adipic acid, anhydrous glycerin, polysorbate 80.

### ***Questions or comments?***

**1-866-467-2748**

## **PRINCIPAL DISPLAY PANEL**

Premier Value®

NDC 68016-793-15

\*COMPARE TO THE ACTIVE INGREDIENT IN DEBROX® DROPS

EAR WAX REMOVAL AID DROPS KIT

Carbamide Peroxide 6.5%

Ear Wax Removal Aid

- Safe & Gentle
- Microfoam Cleansing Action
- Easy to use Instructions

NET WT 0.5 FL OZ (15 mL)

This kit include soft rubber bulb ear syringe and drops

**TAMPER EVIDENT: DO NOT USE IF OUTER CARTON IS OPEN OR TORN**

**IMPORTANT: Keep the carton for future reference on full labeling.**

**Distributed BY:**

**Pharmacy Value Alliance, LLC**

**407 East Lancaster Avenue,**

Wayne, PA 19087

\*This product is not manufactured or distributed by Medtech Products Inc. the distributor of Debrox® Drops.



## EAR WAX REMOVAL AID DROPS

carbamide peroxide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-793
<b>Route of Administration</b>	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	0.065 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
ADIPIC ACID (UNII: 76A0JE0FKJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-793-15	1 in 1 CARTON	04/18/2019	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	04/18/2019	

**Labeler** - PHARMACY VALUE ALLIANCE, LLC (101668460)

Revised: 6/2019

PHARMACY VALUE ALLIANCE, LLC